From the Society for Vascular Surgery

Analysis of EndoAnchors for endovascular aneurysm repair by indications for use

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Objective: **The proximal aortic neck remains one of the challenges of endovascular aneurysm repair (EVAR), and the risk of type Ia endoleak and endograft migration is increased in patients with short, large-diameter, or highly angulated necks. EndoAnchors have been used as an adjunct to EVAR in such patients, and the aim of this study was to assess their benefit analyzed by indication for use.**

Methods: **During a 2-year period, 319 patients were enrolled at 43 sites in the Aneurysm Treatment Using the Heli-FX Aortic Securement System Global Registry (ANCHOR) study. This prospective, multinational, real-world analysis of EndoAnchors comprised two groups of patients, those undergoing first-time EVAR (primary arm, 242) and those with proximal neck complications remote from the time of an initial endograft implantation (revision arm, 77). The primary arm was further subdivided into patients undergoing prophylactic EndoAnchor use for hostile proximal neck anatomy (178), with a type Ia endoleak evident during initial endograft deployment (60), and in conjunction with extender cuffs after unsatisfactory endograft deployment distally in the neck (four). The revision arm was subdivided into patients presenting with a type Ia endoleak alone (45), endograft migration alone (11), and migration with endoleak (21). Technical success was site reported as satisfactory deployment of the desired number of EndoAnchors without fracture or loss of integrity. Procedural success was defined as technical success without type Ia endoleak at completion arteriography. Core laboratory analysis was performed on 249 baseline and 192 follow-up computed tomographic studies, 66 of which were available within the 1-year window.**

Results: **Technical and procedural success rates were highest in the prophylactically treated subset (172 of 178; 96.6%). Whereas the technical success of EndoAnchor deployment was also high in the other subsets, residual type Ia endoleaks were more frequent at completion angiography when the indication for EndoAnchor use was type Ia endoleak, both in the primary arm (17 of 60; 28%) and in the revision arm (9 of 45; 20%). During a median imaging follow-up of 7 months, 183 of 202 patients (90.1%) remained free of type Ia endoleaks. Primary prophylactic patients were free from type Ia endoleak in 110 of 114 cases (96.5%). The most challenging subset was revision patients treated for type Ia endoleak; type Ia endoleaks were evident during follow-up in 10 of 29 of the cases (34%). Sac regression >5 mm in patients with 1-year imaging was observed in 26 of 66 patients (39%) and was highest in the primary prophylaxis subset (20 of 43; 47%).**

Conclusions: **EndoAnchor implantation can be a useful adjunct to EVAR as prophylaxis against proximal attachment site complications in patients with hostile aortic neck anatomy, as treatment for early and late type Ia endoleaks, or, in conjunction with aortic extension cuffs, for endograft migration. Whereas the most challenging patients are those who present with type Ia endoleaks remote from initial EVAR, EndoAnchors are still effective in treating the majority of these cases. (J Vasc Surg 2014;60:1460-7.)**

Complications at the aortic neck represent one of the remaining challenges of endovascular aneurysm repair (EVAR).[1-6] Type Ia endoleaks at the proximal attachment site and loss of fixation with endograft migration continue to occur in even the newest and most technologically advanced devices.[7] Large bare-metal stents, proximal extension cuffs, fenestrated and branched endografts, and external banding have been employed individually and in combination when proximal endograft failure is manifested.[2,8-11]

More recently, the Heli-FX EndoAnchor System (Aptus Endosystems, Sunnyvale, Calif) has been used to

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prevent proximal neck complications in patients with challenging neck anatomy and to treat these complications when they arise.[12] By deploying small helical anchors to affix an endograft to the aortic wall, EndoAnchors provide a degree of sealing and fixation that approximates the strength of an open surgical hand-sewn anastomosis.[13] The clinical outcome after EndoAnchor use for aortic neck complications observed at the time of EVAR or remote from the initial endovascular repair has been reported in the aggregate in the Aneurysm Treatment Using the Heli-FX Aortic Securement System Global Registry (ANCHOR) study.[12,14] Recent publications demonstrated satisfactory short-term success with EndoAnchors.[12,14-17] It is axiomatic that clinical results vary by the specific indication for EndoAnchor use—type Ia endoleak, endograft migration, or unsatisfactory distal deployment in the neck—either at the time of primary EVAR or during follow-up. The current analysis was undertaken to assess clinical and imaging outcome, analyzing results during longer follow-up, segregated by the indication for EndoAnchor use. Such information may be of value to the clinician in weighing the risks and benefits of EndoAnchor use in an individual patient with a specific clinical presentation.

METHODS

The ANCHOR study is a prospective, nonrandomized, dual-arm, multicenter, multinational postmarketing study of the real-world use of the Heli-FX system with EndoAnchors in patients undergoing or who have undergone EVAR for infrarenal abdominal aortic aneurysms. Participating investigators are listed in the Appendix (online only).

Study design. The ANCHOR study was registered on ClinicalTrials.gov on February 9, 2012. Institutional Review Board or Ethics Committee approval was obtained at each site, and each patient provided written informed consent. The study was conducted according to the Declaration of Helsinki, applicable sections of ISO 14155, MEDDEV 2.12-2, and the International Conference on Harmonization Good Clinical Practice guidelines.

Patients with infrarenal abdominal aortic aneurysms were eligible for inclusion in the registry if they were asymptomatic, symptomatic, or presented with aneurysm rupture; had adequate iliofemoral access suitable to accommodate a 16F sheath; and had a life expectancy of 1 year or more. Commercially available endografts that underwent successful testing for EndoAnchor compatibility included the Zenith (Cook, Bloomington, Ind), the Excluder (W. L. Gore, Flagstaff, Ariz), and the AneuRx, Talent, or Endurant devices (Medtronic Vascular, Santa Rosa, Calif). Patients were ineligible for inclusion in the study if they had prior EndoAnchor implantation or significant proximal aortic neck thrombus or calcification. In addition to consenting patients preoperatively, patients could also be consented within 30 days after EndoAnchor implantation. Investigators were asked to enroll such patients before the first postoperative imaging study. This criterion was designed to reduce (but not to eliminate) the potential for selection bias without losing data from patients with unplanned use of the device.

The study population was enrolled into two cohorts: a primary arm, with patients who underwent EndoAnchor implantation during an initial EVAR procedure; and a revision arm, with patients who had EndoAnchor placement remote from the initial EVAR procedure when the patient presented with type Ia endoleak, endograft migration, or both. Aortic extender cuffs were used in conjunction with EndoAnchors at the discretion of the investigator, usually when a significant length of aortic neck was present between the proximal margin of the endograft and the lowest renal artery, either from misdeployment (primary arm) or from postprocedure endograft migration (revision arm). Patients were subcategorized into six subsets by indication for EndoAnchor use. Patients in the primary arm included those with site-reported hostile aortic neck anatomy who were treated for prophylaxis against future neck complications, type Ia endoleak after endograft deployment, or unsatisfactory endograft deployment distally in the aortic neck. The last subset was defined by the investigator as unsatisfactory endograft deployment distally within the aortic neck in the absence of discernible endoleak but requiring deployment of an extension cuff to achieve an acceptable seal zone length. Patients in the revision arm were treated for type Ia endoleak, endograft migration, or both. The current analysis categorizes eight patients in the primary arm initially treated for hostile neck anatomy but who exhibited a type Ia endoleak at the time of endograft deployment within the primary endoleak subgroup and not in the prophylactic subgroup, in contrast to prior publications.[15]

Study device. The Aptus Heli-FX EndoAnchor System and its method of use have been described in prior publications, including photographs of EndoAnchors, the delivery system, and deployment into the aortic wall.[12,13,15-17] The Heli-FX system was initially cleared by the U.S. Food and Drug Administration in 2011 and is indicated to provide fixation and sealing between endovascular aortic grafts and the native artery in patients whose endovascular grafts have exhibited migration or endoleak or are at risk of such complications and in whom augmented radial fixation or sealing is required to regain or to maintain adequate aneurysm exclusion. The system is composed of the Heli-FX Guide, EndoAnchors, and the Heli-FX Applier. The system is intended to provide fixation of an endograft to the aortic wall. The Heli-FX Applier is passed through the lumen of the Heli-FX Guide, and each 4.5-mm-length, 3-mm-diameter helically shaped EndoAnchor is implanted serially around the circumference of the endograft within the proximal aortic neck. EndoAnchors are deployed in a two-stage process that allows retraction of an EndoAnchor and repositioning before final deployment.

End points and definitions. For the purposes of this analysis, the primary and revision treatment arms were subcategorized by the indication for EndoAnchor use. Patients in the primary arm underwent EndoAnchor implantation for one of three indications: (1) prophylaxis against

proximal neck complications, (2) treatment of acute type Ia endoleak, or (3) maldeployment of the endograft at an unsatisfactory location distally in the neck. Patients in the revision arm were implanted with EndoAnchors for either type Ia endoleak or endograft migration, accounting for three subgroups: (1) patients with type Ia endoleak without migration, (2) patients with endograft migration without type Ia endoleak, and (3) those with both.

The index procedure was defined as the initial procedure with EndoAnchors implantation as part of the ANCHOR study. Index procedures within the primary arm index were contemporaneous with EVAR. By contrast, index procedures in the revision arm were defined as the EndoAnchor procedure remote from the initial EVAR and not the original endograft procedure itself. Site-specified clinical end points included technical and procedural success. Technical success was defined when the investigator determined that the desired number of EndoAnchors were implanted, each with adequate penetration of the aortic wall and without EndoAnchor fracture. Procedural success was defined as technical success without type Ia endoleak at completion angiography. Adverse event reporting followed the recommendations specified by the Society for Vascular Surgery reporting standards and guideline documents.[18,19] Aneurysm-related reinterventions were defined as any reintervention within 30 days of the index procedure or any reintervention performed to address complications of the aneurysm, the endograft, or EndoAnchors. EndoAnchor-related reinterventions were defined as those reinterventions performed for type Ia endoleak, endograft migration, or EndoAnchor fracture or embolization.

Imaging studies. Follow-up was performed according to each investigator's standard of care. Societal guidelines were recommended but not required, including computed tomographic (CT) imaging with and without contrast enhancement or without contrast enhancement but with duplex ultrasonography at 30 days, at 12 months, and annually thereafter. Endoleaks at completion arteriography were site reported. Independent core laboratory analyses (Syntactx, New York, NY) were performed on non-contrast-enhanced and contrast-enhanced preoperative and follow-up CT imaging studies. Centerline reformatting and segmentation of CT data sets were performed with iNtuition imaging software (TeraRecon, Foster City, Calif). Imaging end points were measured and reported by the methodology from the Society for Vascular Surgery documents where available.[18,19] The proximal aortic neck length was calculated as the length where the aortic diameter remained no more than 10% greater than the immediate infrarenal diameter. Infrarenal neck angulation was measured with centerline points at the level of the lowest renal artery, at the distal aortic neck, and at the aortic bifurcation. A conical proximal aortic neck was defined as one in which the aortic diameter increased more than 10% from the lowest main renal artery to a point 10 mm distally. Aortic neck calcium and thrombus content was measured and expressed in degrees of circumference where its thickness exceeded 1 mm. Significant mural thrombus or calcium was defined when the average thickness was >1 mm. The proximal aortic neck was considered "hostile" when its length was less than 10 mm, diameter exceeded 28 mm, angulation was more than 60 degrees, or mural thrombus or calcium exceeded 1 mm in average thickness or when the aortic neck was conical. For the purposes of analysis, the 1-year imaging study was specified with a window of 360 ± 90 days.

Data analysis. An electronic data capture system was used (iMedNet, Minnetonka, Minn). Electronic case report forms were verified and electronically signed by each investigator. All elements of the case report forms were remotely monitored by independent clinical monitors. Safety end points were evaluated by an independent medical monitor, both in individual listings and in summary table format. The medical monitor identified any unanticipated adverse device effects that by virtue of severity or incidence, individually or in the aggregate, were not previously described.[19]

This was not a hypothesis-driven study, and for this reason, no sample size calculation was performed. Continuous variables are expressed as mean and standard deviation or, when not normally distributed, as median and interquartile range. Dichotomous end points were calculated as a numerator defined as the number of subjects triggering the end point, divided by a denominator defined as the number of subjects with the end point available for analysis. Differences in continuous variables were evaluated with the Student *t*-test or single-factor analysis of variance. Dichotomous variables were assessed with Fisher exact test when individual cell numbers were <5 and with a standard χ^2 analysis when not. *P* values were considered to be significant when the two-tailed α was $< .05$, and Bonferroni corrections were used for multiple comparisons.

RESULTS

Between February 2012 and December 2013, 319 patients from 43 sites in the United States and Europe were enrolled in the ANCHOR study. Among these, 242 patients (75.8%) were primary cases and 77 (24%) were revisions. The number of patients per site ranged from one to 59 (mean, 7 ± 11). The baseline patient characteristics have been reported previously. In brief, patients had intact aneurysms in 99% of the cases and were most commonly American Society of Anesthesiologists physical status class 3 (71.5%) or class 4 (18.5%). Core laboratory-assessed baseline anatomic characteristics confirmed a hostile aortic neck in 84.1% of patients. The proximal neck was <15 mm in length in 57.4% and <10 mm in length in 39.5%.

Baseline characteristics. Demographic characteristics were similar in the primary and revision arms, but there were significant differences by indication (Table I). The proportion of different endografts also varied between indication subsets (Table II). The most common endograft in the primary arm was the Medtronic Endurant (46.3%). Endografts were more homogeneously distributed in the revision arm, with no one device representing more than 25% of the group.

Table I. Baseline demographics by indication for EndoAnchor use (*P* values are specified in footnotes only for significant differences after Bonferroni correction)

	Primary arm indication			*Revision arm indication*		
Demographic variable	*Prophylaxis*	*Type Ia endoleak*	*Endograft maldeployment*[a]	*Type Ia endoleak*	*Migration*	*Endoleak and migration*
No.	178	60	4	45	11	21
Age, years	72 ± 8	75 ± 8	76 ± 6	77 ± 7	75 ± 7	79 ± 8[b]
Male gender	138 (77.5)	38 (63)	4 (100)	33 (73)	10 (91)	15 (71)
Height, cm	172 ± 16	171 ± 26	178 ± 13	171 ± 9	180 ± 9	173 ± 8
Weight, kg	84.3 ± 20.4	80.2 ± 15.7	74.1 ± 7.0	79.4 ± 18.9	94.5 ± 17.6	90.2 ± 18.7
Body mass index, kg/m^2	28.1 ± 5.8	26.8 ± 4.9	23.6 ± 2.8	26.9 ± 5.4	29.2 ± 5.8	30.2 ± 6.2

Continuous data are presented as mean ± standard deviation and categorical data as number (%).
[a]No statistical testing was performed with respect to this group because of the small number of patients.
[b]$P = .002$ vs primary prophylaxis subset; $P < .001$ vs revisions for endoleak.

Table II. Types of endografts (231 patients with data; percentage indicates the proportion of endografts within a row)

Indication subset	*Endurant, No. (%)*	*Talent, No. (%)*	*AneuRx, No. (%)*	*Zenith, No. (%)*	*Excluder, No. (%)*	*Other, No. (%)*
Primary	112 (46.3)	0	0	39 (16.1)	86 (35.5)	5 (2)
Prophylactic	90 (50.6)	0	0	27 (15.2)	58 (32.6)	3 (2)
Type Ia endoleak	18 (30.0)	0	0	12 (20.0)	28 (46.7)	2 (3)
Distal endograft misdeployment	4 (100)	0	0	0	0	0
Revision	10 (13)	14 (18)	18 (23)	11 (14)	16 (21)	8 (10)
Type Ia endoleak	9 (20)	8 (18)	5 (11)	8 (18)	11 (24)	4 (9)
Endograft migration	0	2 (18)	5 (45)	0	3 (27)	1 (9)
Endoleak and migration	1 (5)	4 (19)	8 (38)	3 (14)	2 (10)	3 (14)
All	122 (38.2)	14 (4.4)	18 (5.6)	50 (15.7)	102 (32.0)	13 (4.1)

Table III. Baseline anatomic characteristics (core laboratory analysis of 249 adequate preoperative imaging studies) by indication for EndoAnchor use

	Primary arm indication			*Revision arm indication*		
Anatomic measure	*Prophylaxis*	*Type Ia endoleak*	*Endograft maldeployment*	*Type Ia endoleak*	*Migration*	*Endoleak and migration*
Images available for core laboratory, No.	138	48	3	37	8	15
Maximum sac diameter, mm	55 ± 11	56 ± 11	60 ± 8	69 ± 18	67 ± 17	65 ± 10
Suprarenal aortic diameter, mm	27 ± 3	27 ± 3	26 ± 3	30 ± 6	34 ± 7	31 ± 6
Infrarenal aortic neck diameter, mm	26 ± 4	26 ± 5	27 ± 7	29 ± 9	29 ± 3	32 ± 7
Infrarenal neck length, mm	17 ± 13	17 ± 9	6 ± 3	13 ± 10	19 ± 13	17 ± 14
Suprarenal angulation, degrees	16 ±12	19 ± 15	11 ± 6	14 ± 9	15 ± 14	13 ± 9
Infrarenal angulation, degrees	34 ± 18	40 ± 19	36 ± 24	37 ± 16	32 ± 8	38 ± 19
Neck thrombus, mm	0.9 ± 1.4	0.3 ± 0.7	0.6 ± 1.1	1.4 ± 4.6	0.7 ± 1.1	0.9 ± 2.8
Neck thrombus, degrees circumference	57 ± 83	21 ± 46	71 ± 124	47 ± 91	51 ± 80	22 ± 62
Neck calcium, mm	1.1 ± 1.3	1.1 ± 1.2	1.8 ± 0.9	0.3 ± 0.9	0 ± 0	0.7 ± 1.2
Neck calcium, degrees circumference	22 ± 32	28 ± 44	22 ± 5	3 ± 9	0 ± 0	12 ± 24
Conical configuration	53 (38.4)	14 (29)	3 (100)	18 (49)	2 (25)	7 (47)
Hostile neck	118 (85.5)	39 (81)	3 (100)	28 (76)	6 (75)	15 (100)

Data are presented as mean ± standard deviation.

The baseline anatomic measures differed by indication for EndoAnchor use (Table III). Aneurysm sac diameter was greater in the revision arm (68 ± 17 vs 56 ± 12 mm; $P < .001$), as was proximal neck diameter (30 ± 7 vs 26 ± 4 mm; $P < .001$). Mural calcium within the proximal neck was greater in the primary arm, with 2 mm or more of mural calcium covering 23 ± 34 vs 5 ± 16 degrees of neck circumference ($P < .001$). Differences in neck length, angulation, mural thrombus content, or the frequency of a conical configuration were not

Table IV. Details of the index procedure and the initial hospitalization

	Primary arm indication			*Revision arm indication*		
Measure	*Prophylaxis*	*Type Ia endoleak*	*Endograft maldeployment*[a]	*Type Ia endoleak*	*Migration*	*Endoleak and migration*
No.[b]	178	60	4	45	11	21
Number of EndoAnchors deployed	5.3 ± 1.7[c]	6.2 ± 2.0	5.8 ± 1.5	7.0 ± 2.5	6.0 ± 2.2	6.3 ± 2.6
Procedure duration, minutes	129 ± 66[d]	165 ± 81	138 ± 69	129 ± 52	123 ± 75	194 ± 116
Fluoroscopy use, minutes	30 ± 13	34 ± 16	35 ± 19	20 ± 8[e]	36 ± 18	34 ± 18
Technical success	172 (96.6)	59 (98)	2 (50)	43 (96)	8 (73)	19 (90)
Procedural success	172 (96.6)	43 (72)	2 (50)	35 (78)	8 (73)	19 (90)
Type Ia endoleak at end of procedure[f]	0 (0)	17 (28)	1 (25)	9 (20)	0 (0)	1 (5)
Intensive care unit, % admitted	37.7	27	100	23	50	48
Length of hospitalization, days	3.9 ± 7.0	4.0 ± 4.9	4.0 ± 2.3	7.0 ± 8.8	2.1 ± 1.3[g]	7.3 ± 9.6

Continuous data are presented as mean ± standard deviation and categorical data as number (%).
[a]No statistical testing was performed for this subgroup because of the small number of patients.
[b]Data on fluoroscopy, intensive care unit admission, and length of hospitalization are based on less than the specified number because of missing values.
[c]$P = .001$ vs primary endoleak subset; $P < .001$ vs revisions for endoleak subset.
[d]$P = .002$ vs primary prophylactic subset.
[e]$P < .001$ vs primary prophylaxis and primary endoleak subsets.
[f]Site-reported type Ia endoleaks on completion angiography after deployment of EndoAnchors. Another endoleak was initially reported to be present after EndoAnchor deployment, but on site monitoring, the endoleak was present before but not after deployment.
[g]$P = .001$ vs revisions for endoleak subset.

significantly different in the two treatment arms. The aortic anatomy met the criteria for a hostile neck in 160 of 189 (84.7%) and 49 of 60 (82%) of the primary and revision patients, respectively ($P = .727$). Within the six subsets of indications for EndoAnchor use, the aortic neck length was shortest in the primary arm patients with unsatisfactory distal endograft deployment (5.5 mm) and in the revision patients with endoleaks (13.5 mm).

Index procedure and hospitalization. Details of the index procedure and hospitalization appear in Table IV. A mean of 5.8 ± 2.1 EndoAnchors was deployed, 5.5 ± 1.8 in the primary arm and 6.7 ± 2.5 in the revisions ($P < .001$). The number of EndoAnchors deployed differed significantly between indication subsets ($P < .001$), with the fewest EndoAnchors deployed in patients treated prophylactically (5.3 ± 1.7) and the greatest number of EndoAnchors in the revision patients treated for endoleak (7.0 ± 2.5). Fewer EndoAnchors were deployed in patients with procedural success, 5.5 ± 1.9 vs 7.6 ± 2.5 ($P < .001$). The duration of the index procedure was similar in the primary and revision arms ($P = .632$) but did differ significantly by indication subset ($P < .001$). Procedure duration was longest in the revisions treated for migration and endoleak (194 ± 116 minutes) and shortest in the revisions treated for endoleak alone (123 ± 75 minutes). Fluoroscopy time was similar in the primary and revision arms ($P = .202$) but was associated with indication subset and was shortest in the revisions treated for endoleak alone (20 ± 8 minutes). Success rates were uniformly high, with significantly higher procedural success in the primary arm ($P = .035$). There were significant differences between the indication subsets, with a lower rate of technical and procedural success when migration was present ($P < .001$). There were 28 type Ia endoleaks reported by the sites at the conclusion of the index procedure, and they were most frequent when the indication for EndoAnchor use was endoleak. Among these, 17 (60.7%) were resolved on the first postoperative core laboratory-assessed CT scan. Patients with type Ia endoleaks at completion angiography had their first postoperative CT study earlier than those without endoleaks, 20 ±18 vs 41 ± 36 days after the index procedure ($P = .013$).

The length of hospitalization averaged 4.5 ± 7.1 days, 3.9 ± 6.5 days in the primary arm and 6.4 ± 8.5 days in the revision arm ($P = .026$). The length of hospitalization was associated with the indication for EndoAnchors ($P = .050$), ranging from 2.1 ± 1.3 days in revision cases treated for migration to 7.0 ± 8.8 days in revisions treated for endoleak alone and 7.3 ± 9.6 days in revisions treated for endoleak with migration.

Postoperative follow-up. Clinical follow-up averaged 16 ± 5 months and did not differ between indications for EndoAnchor use (Table V). There were no significant differences in the frequency of serious adverse events ($P = .416$; Table VI) or all-cause mortality ($P = .434$) within the different indications for EndoAnchor use. Serious adverse events occurred in 43 patients (17.8%) in the primary arm and 18 patients (23.4%) in the revision arm ($P = .276$). The subset with the lowest frequency of serious adverse events was the primary prophylaxis group (15.6%), and the subset with the highest rate of serious adverse events was the revision patients treated for endoleak (33.3%). Renal insufficiency developed in 10 patients (3%). Deaths occurred in 15 patients (4.7%) in the series, and none were device related. One death was procedure related, occurring within 30 days of the index procedure. This patient experienced perioperative bleeding complications unrelated to EndoAnchor use and expired on postoperative day 12 from multiorgan system failure.

There were 33 aneurysm-related reinterventions occurring in 22 (6.9%) of the 319 study patients. Among the

Table V. Clinical outcome during follow-up

Indication for EndoAnchor use	*No.*	*Follow-up, mean ± SD, months*	*Serious adverse events,*[a] *No. (%)*	*All-cause death, No. (%)*	*Aneurysm-related reinterventions,*[b] *No. (%)*	*EndoAnchor-related reinterventions, No. (%)*
Primary	242	16 ± 5	43 (17.8)	11 (4.5)	11 (4.5)	2 (2.2)
Prophylaxis	186	16 ± 5	29 (15.6)	7 (4)	8 (4)	0 (0)
Type Ia endoleak	52	15 ± 5	13 (25)	3 (5)	3 (5)	2 (3)
Endograft maldeployment	4	17 ± 6	1 (25)	1 (25)	0 (0)	0 (0)
Revision	77	16 ± 6	18 (23)	4 (5)	11 (14)	5 (6)
Migration	11	17 ± 5	1 (19)	0 (0)	3 (27)	0 (0)
Type Ia endoleak	45	17 ± 6	10 (22)	3 (7)	6 (13)	4 (9)
Migration and endoleak	21	16 ± 6	7 (33)	1 (5)	2 (10)	1 (5)
All	319	16 ± 5	61 (19.1)	15 (4.7)	22 (6.9)	7 (2)

SD, Standard deviation.
[a]Serious adverse events are tabulated by patient. The percentage denotes the proportion of patients within a subgroup who experienced an event.
[b]The number of aneurysm-related reinterventions is tabulated by patient; a patient who had more than one reintervention is listed only once. All EndoAnchor-related reinterventions are also aneurysm-related reinterventions.

Table VI. Serious adverse events

Category	*No. of events (%)*
Vascular	
Access vessel injury	3 (5)
Endograft limb occlusion	1 (2)
Lower extremity ischemia	7 (11)
Renal artery stenosis/renal embolus	3 (5)
Rupture thoracic aortic aneurysm	1 (2)
Respiratory	
Pneumonia	2 (3)
Respiratory failure	4 (7)
Endoleaks	
Type Ia endoleak	2 (3)
Type II endoleak	2 (3)
Type III endoleak	1 (2)
Cardiac	
Myocardial infarction	2 (3)
Congestive heart failure	4 (7)
Arrhythmia	1 (2)
Neurologic	
Stroke	2 (3)
Paraparesis	1 (2)
Other	
Bleeding at operative site	7 (11)
Urologic	3 (5)
Gastrointestinal	4 (7)
Local wound complications	1 (2)
Fever	1 (2)
Other, unrelated	9 (15)
All serious adverse events	61 (100)

reinterventions, 14 were for type Ia endoleak, nine for type II endoleak, and four for endograft limb occlusion. Aneurysm-related reinterventions were more frequent in the revision arm (11 of 77; 14.3%) compared with primary cases (11 of 242; 4.5%; $P = .008$). A patient who was enrolled with a type Ia endoleak remote from initial endograft implantation had persistence of the endoleak despite repeated percutaneous interventions. This patient eventually underwent open surgical conversion 1 year after EndoAnchor implantation. CT imaging revealed an undersized endograft with a 4-mm gap between the graft and the wall of the proximal neck. There were 15 EndoAnchor-related reinterventions in seven patients (2%). The frequency of EndoAnchor-related reinterventions was higher in the revision arm (5 of 77; 6%) than in the primary arm (2 of 242; 1%; $P = .010$).

Type Ia endoleaks were observed in 19 of the 202 patients (9.9%) with CT imaging assessed by the core laboratory (mean imaging follow-up, 7 ± 6 months; Table VII). The highest rate of type Ia endoleak on follow-up CT occurred in the subset of revision patients with type Ia endoleak as the indication for EndoAnchors use, with an observed frequency of 10 of 29 (34%). The primary patients undergoing prophylactic use of EndoAnchors had the lowest rate of type Ia endoleaks in follow-up, occurring in four of 114 patients (4%). Aneurysm sac diameters were available in 66 patients with 1-year follow-up CT imaging available. Sac regression of >5 mm was observed in 26 patients (39%). The frequency of aneurysm sac regression was highest when EndoAnchors were placed for prophylaxis of aortic neck complications, occurring in 20 of the 43 patients in that subset (47%). When analyzed by sac diameter change per month of observation, the average change was 0.12 mm/month with a high degree of variability (standard deviation, 1.3 mm/month) and without statistical difference between the six indication subsets ($P = .219$). Aneurysm sac enlargement was observed in one case (one of 66; 2%). This patient was in the revision arm and presented with endograft migration. Despite deployment of an aortic extension cuff and EndoAnchors, CT imaging at 10 months after the procedure documented 6 mm of sac enlargement without appreciable endoleak.

DISCUSSION

Since the advent of EVAR by Parodi with the first five cases reported in 1991, devices have undergone considerable technologic development. The field has witnessed significant improvements in metallic materials and their preparation, fabrics, methods of affixing fabric to the stent skeleton, and size and ease of use of delivery systems. In parallel, there have been improvements in operator skills and availability of better imaging equipment. Singularly and in concert, the evolution of device design and clinical care has enhanced the safety and durability of the procedure.

Table VII. Imaging outcome (core laboratory reported; 202 follow-up imaging studies)

Indication for EndoAnchor use	*Follow-up, mean ± SD, months*	*Type Ia endoleak, n/N (%)*	*Endograft migration*	*Sac regression (>5 mm),[a] n/N (%)*	*Sac enlargement (>5 mm),[a] n/N (%)*
Primary	7.1 ± 5.5	8/158 (5)	0	22/52 (42)	0/52 (0)
Prophylaxis	7.4 ± 5.9	4/114 (4)	0	20/43 (47)	0/43 (0)
Type Ia endoleak	5.9 ± 3.9	4/41 (10)	0	2/8 (25)	0/8 (0)
Endograft maldeployment	7.3 ± 6.2	0/4 (0)	0	0/1 (0)	0/1 (0)
Revision	7.3 ± 5.7	11/44 (25)	0	4/14 (29)	1/14 (7)
Endograft migration	8.4 ± 5.6	0/6 (0)	0	0/3 (0)	1/3 (33)
Type Ia endoleak	6.7 ± 6.2	10/29 (34)	0	2/8 (25)	0/8 (0)
Migration and endoleak	8.3 ± 4.5	1/9 (11)	0	2/3 (67)	0/3 (0)
All	7.1 ± 5.6	19/202 (10)	0	26/66 (39)	1/66 (2)

SD, Standard deviation.
[a]Tabulated for 66 patients with available 1-year computed tomography (CT) imaging studies.

Device-related complications, however, continue to occur after EVAR. The rate of type Ia endoleak and endograft migration, albeit reduced during the last two decades, remains significant in patients with hostile proximal neck anatomy.[20] As well, inadvertent deployment of an endograft distally within the aortic neck occasionally occurs, whether from inadequate imaging during release or as a result of distal slippage within a conical neck. These complications occur at a higher rate in a real-world clinical use compared with the initial trials for regulatory approval, an observation that may be related to off-label use in patients with challenging aortic anatomy.[21,22] The frequency of proximal neck complications may be influenced by device design improvements, advances that may embolden clinicians to treat more anatomically challenging cases.[23]

We previously reported the intermediate-term outcome of the ANCHOR trial in the aggregate.[15] The current report comprises a closer evaluation of outcome in six specific indications for EndoAnchor use with additional follow-up. Among these, all but the primary prophylactic subset encompass EndoAnchor use to treat an existing problem: type Ia endoleak, unsatisfactory position of an endograft, or both. The outcome after EndoAnchors use in the primary prophylaxis subset was excellent, but it is clear that their ultimate utility cannot be assessed without the availability of longer term follow-up data. The risk of endograft complications at the proximal neck increases over time, and the current intermediate-term follow-up is insufficient for definitive conclusions to be drawn. By contrast, the utility of EndoAnchors for treatment of existing complications may be at least in part assessable with shorter follow-up. Whereas the rate of recurrent endoleak and migration may increase over time, the finding of successful intermediate-term remediation of existing problems is promising.

The current analysis focused on the six general categories of indication for EndoAnchor use. Among the three indication subsets in the primary arm, the best results were achieved in the prophylaxis subgroup. Although the ultimate value of EndoAnchors in the prevention of long-term complications will require longer follow-up data, the observed 3.5% rate of type Ia endoleak is lower than the 10% rate reported in prior studies.[5,6,24] As well, the ANCHOR study used core laboratory CT assessment of endoleaks, whereas prior series were, by and large, limited to site-reported imaging findings. Thus, differences in outcome must be considered in the context of the different populations studied and end point definitions.

In patients with type Ia endoleaks evident on angiography after endograft deployment, EndoAnchors resulted in resolution of the endoleak in approximately 90% of cases. EndoAnchor use as an adjunct to aortic extension cuff deployment in patients with endograft maldeployment distally in the neck was uniformly successful, but only four patients fell within this indication. These patients represented a small subset with an extreme degree of neck hostility.

In the revision arm, three indication subsets comprised those with endograft migration, type Ia endoleak, or both, treated remote from the initial EVAR procedure. Newer generation devices appeared less often in the subgroup of patients presenting with both endoleak and migration. Whereas this observation prompts consideration of endoleak with migration as a device-related event, one cannot exclude longer follow-up as the explanation for the finding. These subsets are characteristically among the most difficult to treat, often having failed numerous prior reinterventions, with EndoAnchor use as a final effort for cure. Fenestrated and branched endografts offer one potential solution in such patients, but the use of the only U.S. Food and Drug Administration-approved fenestrated device is restricted by angulation (<45 degrees) and neck length (≥4 mm).[25] A recent series from the Cleveland Clinic reported on the use of fenestrated and branched endografts in 54 patients presenting with proximal neck failure remote from EVAR,[11] somewhat analogous to the ANCHOR revision arm. The fenestrated and breached endograft procedures were complex, with an average duration of approximately 5 hours and requiring 93 mL of contrast material use and 83 minutes of fluoroscopy, in each case, two to three times what was observed in the ANCHOR revision subgroup. Technical deployment failures occurred in 15% of patients. Type Ia endoleaks were uncommon after fenestrated or branched rescues, occurring in only one patient (2%). However, renal insufficiency developed in 10% of patients, and secondary interventions were required in 29% of the series.

Resolution of proximal endoleaks was observed in all but one of the 15 patients with core laboratory imaging

assessment after EndoAnchor and extension cuff treatment for migration with or without endoleak. The subset of revision patients treated for type Ia endoleak alone was perhaps the most challenging. These patients had very short neck lengths, with almost half below 10 mm in length. More important, these patients demonstrated endoleaks in the presence of satisfactory endograft position within the aortic neck. Despite the inability to effectively address any diameter mismatch between an endograft and neck diameter, approximately two thirds of these patients were effectively treated with EndoAnchors without residual or recurrent proximal endoleaks in follow-up.

CONCLUSIONS

EndoAnchors can be a useful adjunct to EVAR in treating postoperative complications that arise during or after endograft implantation and for prophylaxis in patients with challenging aortic neck anatomy. Whereas EndoAnchors can be effectively used to treat late type Ia endoleaks remote from EVAR, the success rate is lower than when such leaks are identified and treated with EndoAnchors at the time of the initial aneurysm repair.

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Analysis and interpretation: JD, KO, MM, DV, WM, FA, JJ, WJ
Data collection: KO
Writing the article: JD, KO, WJ
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Obtained funding: JD, KO, WJ
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